

CFAR Supplement Announcement in HIV/AIDS –FY2012

The CFAR Program at the National Institutes of Health (NIH) invites applications from currently funded CFARs for administrative supplements.

Purpose

The purpose of this administrative supplement opportunity is two-fold:

- To support a broad range of highly innovative research projects and pilot studies to address key gaps in our understanding of HIV/AIDS.
- To support new investigators who have not yet received an NIH award in AIDS research as well as established investigators in non-HIV fields who have never received an NIH research award for HIV/AIDS studies. This funding will provide support for development of preliminary data to support an NIH research project grant application.

Background and Scientific Areas of Interest

CFARs are strongly encouraged to design projects appropriate for collaboration with investigators and disciplines not usually involved in HIV research. Involvement and mentoring of junior scientists is strongly encouraged. This opportunity should build research capacity at the CFAR institution in the scientific areas specified below and is intended to complement ongoing domestic and international HIV/AIDS research efforts funded or sponsored by the NIH. International collaborations should respond to the research priorities in the foreign country.

1. HIV-TB Co-infection

HIV infection is the strongest risk factor for developing tuberculosis (TB). TB co-infection is the leading cause of mortality among those infected with HIV worldwide. Despite the significance of the problem, major gaps exist in our basic understanding of the pathogenic interactions between HIV disease and TB and the immune system.

The purpose of these administrative supplements is to support highly innovative research on the effects of HIV infection on *M. tuberculosis* (MTB) infection throughout the clinical spectrum of TB infection and disease. Topics relevant to this funding opportunity include, but are not limited to:

- biomarkers to differentiate between anergic response to current Tuberculin skin tests or Interferon Gamma Release Assay (TST/IGRA) tests and true non-infection
- cellular mechanisms associated with *M. tuberculosis* (MTB) death, survival, and/or proliferation in the full panoply of cellular types associated with TB infection such as macrophages, T-cells, and alveolar epithelial cells;
- mechanisms of innate immune control (or loss thereof) of latent TB infection
- understanding the humoral immune response and its variability throughout the course of infection
- characterizing bacterial processes (at the cellular level and the bacterial population level) in the setting of a depressed immune system
- host and pathogen mediated mechanisms of MTB latency such as neutralization of host defenses, bacterial metabolic adaptations and development of drug tolerance, and associated targets for potential therapeutic interventions.

Novel assay and bio-imaging/technology development, and animal model development that will lead to enhancing this area of research will be considered responsive. Translational studies or studies with clear translational potential are encouraged.

Supplement awards are for **one year** with maximum funding per application of **\$100,000 Direct Costs**. A maximum of **one application** can be submitted per eligible CFAR.

2. Ethical Issues in HIV/AIDS Research Involving Specimens

Research with clinical (human) specimens is vital to progress in biomedical science and public health. International collaborative research involving specimens can involve ethical, legal and political complexities that sometimes stymie important projects. One critical issue is whether communities and ethics boards are fully informed and aware of the realities of research involving human specimens. Significant misconceptions may exist about what types of scientific investigations are conducted with specimens and knowledge of actual risks and public health benefits of this research may be limited. Research which involves genetics may raise particular concerns among some of the stakeholders.

This supplement supports pilot projects to address stakeholder knowledge about HIV/AIDS research involving human specimens. Research in this area can include ethical issues in the use of stored samples (biorepository) or the process for collection of new samples. Topics relevant to this funding opportunity include, but are not limited to studies addressing one of the following aims:

- To gather information on views of stakeholders, including perceptions and misconceptions about risks and benefits of research with biological specimens;
- To gather quantitative data about occurrence of harms, if any, due to specimen research;
- To assess potential and actual benefits of human specimen research;
- To develop mechanisms for education, and communication among stakeholders; and
- To explore and develop new models for shared decision-making regarding oversight of human specimen research in multi-national research collaborations.

CFARs are strongly encouraged to collaborate with Centers or Departments of Bioethics within their universities.

Supplement awards are for **one year** with maximum funding per application of **\$30,000 Direct Costs**. A maximum of **one application** can be submitted per eligible CFAR.

Eligibility

The grantee institution must have a currently funded CFAR with at least one year remaining in its current project period at the time of the supplement award. CFARs are encouraged to collaborate with other CFARs. Core and Scientific Working Groups within the CFAR are encouraged to collaborate on their applications, and to collaborate with appropriate individuals not currently involved in AIDS research. Contact Ann Namkung Lee to discuss eligibility.

Project leaders are restricted to new investigators (please see [NIH definition of new investigator](#)) and to established investigators in non-HIV fields who have never received an NIH research award for

HIV/AIDS studies. Mentorship and collaboration with established AIDS investigators is strongly encouraged.

Studies that are an expansion of previously funded CFAR supplements or funded NIH applications are not eligible for funding under this announcement.

Application Instructions

Applications must be submitted before or on **May 14, 2012**. Requests submitted in response to this opportunity must use the PHS 398 forms (rev. 6/2009; available at <http://grants1.nih.gov/grants/funding/phs398/phs398.html>) and include the following elements in the request packet as described below. Applicants are strongly encouraged to submit applications electronically as an e-mail attachment in PDF format; however, the signature of the institutional official must be clearly visible. Font size restrictions apply as designated within the PHS398 instructions

1) **Cover Letter** – Citing this Supplement Announcement, a request for an Administrative Supplement, and the following information:

- CFAR Principal Investigator and Supplement Project Director names
- Parent grant number and title
- The scientific area of interest for this supplement request
- Amount of the requested supplement
- Name and title of the authorized institutional official
- Phone, email, and address information for the PI, the PD and the institutional official

The cover letter must be signed by the authorized organizational representative/institutional official.

2) **PHS 398 Form Page 1** (Face page) (MS Word PDF) – Provide requested information as follows:

- The title of the project (Box 1) should be the title of the parent award and a descriptive title of the supplement application
- The scientific area of interest should be cited under title in Box 2, and the “yes” box should be checked;
- Enter name of CFAR PI and the name of the project director. (Example: Dr. Bill Jones (CFAR PI) and Dr. John Smith (Project Director)).
- The remaining items on the face page should be filled out in accordance with the PHS 398 application instructions.

3) **PHS 398 Form page 2**

Note: The project “summary” is that of the administrative supplement, not the parent grant. All other information requested on Form Page 2 should be provided.

4) A **brief proposal** describing the project (with parts 4a and 4b not exceeding five pages in total), should include:

- a. An introduction that clearly states the **scope of the overall project** and the anticipated contribution of the requested supplement.
- b. The **research project plan** should include the background and rationale for the proposed study; a description of the activities to be undertaken, and roles of key staff; expected outcome of these activities; expected follow-up plan upon completion of the supplement; a description of

- how the supplement and follow-up plan are expected to achieve this outcome (“value-added”); and plans to monitor and evaluate the ability of the activities to achieve the outcome. Most importantly, applicants must clearly indicate how the proposed research activities are expected to lead to development of the stated goals. Mentorship and collaborations must be explained.
- c. **Budget** for the supplement with a justification that details the items requested, including Facilities and Administrative costs and a justification for all personnel and their role(s) in this project. Note the budget should be appropriate for the work proposed in the supplement request.
 - d. **Biographical Sketch** for all new Senior/Key Personnel. [MS Word](#) [PDF](#)
 - e. **Human Subjects/Vertebrate Animal documentation** (if applicable). Include a current Human Subjects/Institutional Review Board (IRB) or Vertebrate Animals/Institutional Animal Care and Use Committee (IACUC) approval letter, if applicable. Otherwise, this letter will be required at time of funding. All appropriate IRB and IACUC approvals must be in place prior to a supplement award being made. NOTE: Studies involving clinical trials are not allowed.
 - f. Further NIH-initiated administrative actions are required for ALL international studies (NOTE: this also includes the CFAR International Checklist requirement) and any clinical studies deemed above minimal risk or involving vulnerable populations.
 - g. **PHS 398 Checklist Form** [MS Word](#) [PDF](#)
 - i. TYPE OF APPLICATION. Check SUPPLEMENT box and enter your CFAR grant number;
 - ii. Applicants must state that all federal citations for PHS grants will be met (e.g., human subjects, animal welfare, data sharing, etc.
 - h. NO other support. This information will be required for all applications that will be funded. NIH will request complete and up to date “other support” information at an appropriate time after review.
 - i. NO resource page (unless there are new resources that will be used for this study)
 - j. NO appendices

Budget and Funding Information

Funding for supplements in HIV-TB co-infection will be supported by the National Institute of Allergy and Infectious Diseases (NIAID) and funds for Ethical Issues in HIV/AIDS Research Involving Human Specimens will be provided by the NIH Office of AIDS Research.

The maximum funding allowed per application is described within each scientific area of interest above.

Funding for administrative supplements to existing CFAR grants will be available for one-year in FY2012 only unless otherwise stated.

Awards are dependent upon the scientific merit of the applications and funding availability.

How to Apply

This is a one-time announcement.

Do not send applications to the NIH Center for Scientific Review.

Applications must be signed by the authorized institutional official and submitted on or before **May 14, 2012** to the Program Officer listed below. If an application is received after that date, it will be returned to the applicant without review.

Ann Namkung Lee
Program Officer
Basic Sciences Program
Division of AIDS
National Institute of Allergy and Infectious Diseases, NIH, DHHS
6700-B Rockledge Drive, Room 4211
Bethesda, MD 20892-7620
Telephone: (301) 496-9176
Email: anamkung@niaid.nih.gov

Submit a letter(s) of collaboration endorsing the proposed study from each of the following participants: investigator performing the study and any collaborators, foreign investigator(s) (if applicable), foreign institution (if applicable).

[Applicants are strongly encouraged to submit applications electronically as an e-mail attachment in a single PDF file to the Program Officer; however, the signature of the institutional official must be clearly visible. Applicants may submit applications in paper format, although paper applications are strongly discouraged. Do NOT send both an electronic and a paper version of the same administrative supplement.]

Review Considerations

Upon receipt, applications will be reviewed by the CFAR Program Officer for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to this announcement, the application will be returned without review.

Applications that are complete and responsive to the announcement will be evaluated for scientific and technical merit by an internal NIH review group convened by the NIAID in accordance with standard NIH review procedures.

Review Criteria

The following criteria apply to all applications. Each of these criteria will be addressed and considered by the reviewers, weighing them as appropriate for each request. The administrative supplement request does not need to be strong in all categories in order for it to receive a favorable evaluation. Factors to be considered in the evaluation of each application include:

Significance – The effect that a collaborative administrative supplement would have on the development of research in the stated scientific area of interest at the institution(s).

1. Evidence that the proposed project(s) will enhance new multidisciplinary collaborations, which may include international collaboration, collaboration with industry, collaboration with junior or minority investigators, collaboration with other CFAR sites, or collaboration with investigators inside or outside of CFAR who have expertise in the stated scientific area of interest;
2. The extent to which the supplement will address development of new strategies for the field of HIV/AIDS (“value-added” of the supplemental monies);

Approach – The quality of the CFAR scientific project proposed, including planning, management, and training (as appropriate) process.

3. Project design and appropriate Core selection;
4. Utilization of existing resources and/or development of unique and appropriate expertise, technology, and resources at the CFAR institution(s), and at the international site, as appropriate;
5. The adequacy of the described plans to monitor the impact of the competitive supplemental award;
6. The quality and appropriateness of mentorship and collaboration;

Innovation - The identification of a unique approach to solve a significant question or gap in the field of HIV/AIDS specifically in the scientific area of interest indicated.

7. The degree of variety/novelty of scientific disciplines that is included in proposed scientific project;
8. The degree of innovation in project selection and experimental design;

Investigator - Choice of appropriate scientists to lead the identification and development of the collaborative administrative supplement project.

9. Choice of appropriate competitive supplement project leader and participating investigators for individual collaborative projects proposed: scientific qualifications, commitment, and experience;
10. The choice of collaborators and mentors available within and outside of the CFAR, as appropriate;

Environment – The likelihood that the proposed project will lead to the development of a new strategy in the scientific area of interest indicated.

11. Availability of appropriate scientific expertise;
12. The potential and intent to collaborate with other institutions and to coordinate program activities with related efforts of other CFARs, NIH programs, other federal agencies (e.g., CDC and USAID), international organizations (e.g., UNAIDS), and NGOs;
13. Evidence that scientific collaborative areas and projects arise from the complementary scientific environment at the CFAR institution(s);

In addition, for applications involving international collaborations:

14. The demonstration of interest in international collaboration with scientists from developing countries, and emerging democracies, and institutions included in the proposed competitive supplement;
15. The demonstration of continued or of future support for the program from governments, and either institutions or other non-governmental organizations from collaborating countries.

Reviewers will also examine the appropriateness of the budget, in consideration of the research environment, for the scientific projects and cores.

Allowable Costs

Funding may be requested for any category normally funded by a CFAR grant that is required to fulfill the goals of the proposed study, and must be fully justified.

Please contact the CFAR Program Officer if you are considering a project that involves a foreign component.

Schedule for Applications

<i>Announcement Release Date:</i>	3/16/12
<i>Application Receipt Date:</i>	5/14/12
<i>Review Date:</i>	5/21/12
<i>Earliest Anticipated Award (Start) Date:</i>	6/15/12

Terms of Award

A formal notification in the form of a Notice of Award (NoA) will be provided to the grantee organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Reporting

Awarded administrative supplements will be required to submit a progress report to be included in the annual progress report of the parent grant.

Award Criteria

The following will be considered in making awards:

- quality of the proposed project as determined by the NIH convened internal review panel, and relevance to the ability of the proposed project to lead to scientific advances in the field of HIV;
- funding availability;
- program and geographic balance among the scientific areas.

Inquiries

Prospective applicants are strongly encouraged to discuss their applications, including proposed collaborating countries and institutions, with the NIH contacts below.

For questions concerning eligibility of the CFAR to respond to this announcement, and any other administrative issues:

Ann Namkung Lee, M.P.H.
Program Officer
Basic Sciences Program
Division of AIDS
National Institute of Allergy and Infectious Diseases, NIH, DHHS

6700-B Rockledge Drive, Room 4211
Bethesda, MD 20892-7626
Telephone: (301) 496-9176
Email: anamkung@niaid.nih.gov

For questions concerning a specific scientific area of interest:

- HIV-TB Co-infection

Sudha Srinivasan, Ph.D.
Program Officer
Tuberculosis Clinical Research Branch
Therapeutics Research Program
Division of AIDS
National Institute of Allergy and Infectious Diseases, NIH, DHHS
6700B Rockledge Drive, Room 4253
Telephone: (301) 402-5765
Email: sudha.srinivasan@nih.gov

- Research Ethics and HIV Clinical Specimens

Liza Dawson, PhD
Team Leader, Research Ethics Team
Basic Sciences Program
Division of AIDS
National Institute of Allergy and Infectious Diseases, NIH, DHHS
6700B Rockledge Drive, Room 4114
Bethesda, MD 20892
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For questions concerning budget and fiscal matters:

Julie Waugh
Grants Management Specialist
Division of Extramural Activities
Grants Management Program
National Institute of Allergy and Infectious Diseases, NIH, DHHS
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